
Clean Patient Information Leaflet

SCHEDULING STATUS: [S4]

SYNALAR SCALP OIL

(Topical scalp oil)

Fluocinolone acetonide

Read all of this leaflet carefully before you start using SYNALAR SCALP OIL:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- **SYNALAR SCALP OIL** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What **SYNALAR SCALP OIL** is and what it is used for
2. What you need to know before you use **SYNALAR SCALP OIL**
3. How to use **SYNALAR SCALP OIL**
4. Possible side effects
5. How to store **SYNALAR SCALP OIL**
6. Contents of the pack and other information

1. What SYNALAR SCALP OIL is and what it is used for

The active ingredient in **SYNALAR SCALP OIL** is fluocinolone acetonide. This medicine reduces inflammation (swelling), redness, pain and itching.

SYNALAR SCALP OIL is used for the treatment of psoriasis of the scalp in adult patients.

It belongs to a group of medicines called corticosteroids.

2. What you need to know before you use SYNALAR SCALP OIL

Do not use SYNALAR SCALP OIL:

- if you are hypersensitive (allergic) to fluocinolone acetonide or any of the other ingredients of **SYNALAR**



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SCALP OIL (listed in section 6).

- If you have any other infections on your skin, or if you suffer from rosacea (redness of your face), acne, or any skin disease around your mouth.
- If you are pregnant.

Warnings and precautions

Take special care with **SYNALAR SCALP OIL**:

- Topical corticosteroids like **SYNALAR SCALP OIL** when used over large areas for prolonged periods and under an occlusive dressing can be absorbed into the bloodstream and cause reversible adrenal suppression (inability to produce adequate amounts of cortisol, a hormone your body needs to cope with physiological stress).
- Children and infants are particularly susceptible to adrenal suppression related to use of topical corticosteroids.
- If you have a peanut allergy or sensitivity.
- If you are planning to become pregnant.
- If you are breast feeding.

Other medicines and SYNALAR SCALP OIL:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

SYNALAR SCALP OIL should not be used during pregnancy and should be used with caution if you are breastfeeding your baby.

Driving and using machines

It is not always possible to predict to what extent **SYNALAR SCALP OIL** may interfere your daily activities.

You should ensure that you do not engage in the above activities until you are aware of the measure to which

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SYNALAR SCALP OIL affects you.

SYNALAR SCALP OIL contains a peanut-derived oil:

SYNALAR SCALP OIL contains an oil which is made from peanuts. If you suffer from nut allergies, you should use **SYNALAR SCALP OIL** with caution. If you notice any sign of hypersensitivity e.g. itching, rash when using **SYNALAR SCALP OIL** you should stop using the medicine immediately.

3. How to use SYNALAR SCALP OIL:

Do not share medicines prescribed for you with any other person.

Always use **SYNALAR SCALP OIL** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Dosage:

For the treatment of scalp psoriasis, wet or dampen hair and scalp thoroughly. Apply a thin film of **SYNALAR SCALP OIL** on the scalp, massage well and cover the scalp with the supplied shower cap. Leave on overnight or for a minimum of 4 hours before washing off. Wash hair with regular shampoo and rinse thoroughly.

If you use more SYNALAR SCALP OIL than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use SYNALAR SCALP OIL

Do not use a double dose to make up for forgotten individual doses. Skip the missed dose and continue with the next scheduled dose.

4. Possible side effects

SYNALAR SCALP OIL can have side effects.

Not all side effects reported for **SYNALAR SCALP OIL** are included in this leaflet. Should your general health

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worsen or if you experience any untoward effects while taking **SYNALAR SCALP OIL**, please consult your health care provider for advice.

If any of the following happens, stop using **SYNALAR SCALP OIL** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Severe rash or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **SYNALAR SCALP OIL**. You may need urgent medical attention or hospitalisation.

Serious side effects such as Cushing's syndrome (a hormonal disorder) may be associated with

- systemic absorption from improper or excessive use of topical corticosteroids. Adrenal suppression, linear growth retardation, delayed weight gain and intracranial hypertension (increased pressure around the brain) have also been reported with the use of topical corticosteroids in infants and children.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor as soon as possible if you notice any of the following:

Common side effects:

- Redness, burning, itching, irritation, rash
- Loss of skin colour (hypopigmentation)
- Darkening of skin colour (hyperpigmentation)
- Abscess (skin infection)

Other side effects reported with the use of topical corticosteroids in general include:

- Dryness, inflammation of hair follicles, abnormal hair growth
- Stretch marks
- Secondary infection, acne
- Allergic skin reaction
- Miliaria (heat rash)
- Skin thinning

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- Rash around the mouth
- Increased blood sugar

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **SYNALAR SCALP OIL**.

5. How to store SYNALAR SCALP OIL

Store at or below 25 °C.

Protect from light and moisture.

Keep the White Opaque PET bottle tightly closed and in the carton until required for use.

Do not refrigerate or freeze.

Store all medicines out of reach of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SYNALAR SCALP OIL contains

The active substance is fluocinolone acetonide.

The other ingredients are isopropyl alcohol, isopropyl myristate, Oleath – 2, peanut oil, light mineral oil and anhydrous citric acid.

What SYNALAR SCALP OIL looks like and contents of the pack

White Opaque PET bottle with White Opaque LDPE Nozzle, a 20 mm PET Neck which is capped with a 20 mm RBD screw cap having foam liner and a 20 mm White ribbed OPQ spout cap, containing 118.28 ml of a clear, colourless to light straw-coloured liquid.



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1.3.2 Patient information leaflet
SYNALAR SCALP OIL (Fluocinolone acetonide, Topical scalp oil)
Date: 19 September 2023
Application numbers: 550064



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Each bottle is packed in an outer cardboard carton with 2 shower caps.

Holder of Certificate of Registration

Glenmark Pharmaceuticals South Africa (Pty) Ltd

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1684

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